

**REMARKS**

By this Amendment, claims 1, 2, 15, 21 and 25-27 have been amended. Support for the instant amendments is provided throughout the as-filed application. No new matter has been added. Thus, claims 1-5, 7-11, 15-19, 21, 22, and 25-27 are pending, of which claims 8-11 and 17-19 are withdrawn from consideration.

In view of the foregoing amendments and the following comments, allowance of all the claims pending in the application is respectfully requested.

As a preliminary matter, Applicant notes that claim 2 was previously amended (although its status identifier had inadvertently stated that the claim was both amended and cancelled).

**CLAIM OBJECTION**

Claim 2 was objected to for allegedly failing to further limit the subject matter of claim 1, for which it depends. In particular, the Examiner asserts that “the limitation that ‘the body portion ... is provided with an inner cavity’ does not further limit the subject matter of claim 1, as claim 1 already recited that the body portion is provided with an inner cavity.” [Office Action, page 4]. Applicant traverses this objection.

Claim 2 recites additional subject matter which was not recited in claim 1. In fact, the Examiner apparently omitted mentioning claimed subject matter in the Office Action using the ellipsis (“...”) in addition to failing to mention other features of claim 2 that follow the above-mentioned quotation. Thus, claim 2 does further limit the subject matter of claim 1. However, solely in an effort to expedite prosecution and in no way acquiescing to the propriety of the objection, Applicant has amended claim 2 to remove the subject matter that was also recited in claim 1.

Accordingly, the withdrawal of the objection of claim 2 is earnestly sought.

**REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. In particular, the Examiner maintains that:

Applicant submits that the elected embodiment of Figures 2-5 teaches the flow of fluid up to regions 1141 and 1142. However, in relation to Figures 2-5, it is not described that fluid flow in regions 1141 and 1142 is contacted with the back surface of the septum. In Figure 4, it appears that fluid contacts the slit surface of the septum, not the back surface of the septum, as the back surface of the septum is not exposed. Paragraphs [0034][0044], as cited by Applicant, of the Specification do not positively recite that it is specially the back surface of the septum that is contacted by the first fluid. Rejection is mentioned.

[Office Action, pages 2-3].

Applicant traverses this rejection for at least the following reasons. The enablement requirement refers to the requirement of 35 U.S.C. § 112, first paragraph, that the specification describe how to make and use the claimed invention. Whether the specification “*positively recites*,” the claimed invention with respect to one embodiment, is not the correct standard for determining enablement.<sup>1</sup> Rather, all that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art, without undue experimentation. *See United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). And the scope of enablement need only bear a “*reasonable correlation*” to the scope of the claims. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

That being said, Figure 14 of Applicant’s Specification clearly shows “at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating

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<sup>1</sup> Applicant further points out that the enablement requirement of 35 U.S.C. § 112, first paragraph, is separate and distinct from the description requirement which requires that the “specification shall contain a written description of the invention.” *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). The Examiner, though, previously withdrew the written description rejection and noted that it was the Pre-Appeal Panel’s decision that the aforementioned limitation is “not new matter as the imitation is discussed with respect to Figure 14.” Interview Summary mailed September 21, 2010.

first fluid redirected by the circulating plate.” And the Examiner previously *acknowledged* that “the limitation is discussed with respect to Figure 14.” Interview Summary mailed September 21, 2010. As such, it was legal error for the Examiner to ignore or disregard Figure 14 for the purposes of determining enablement for the claimed invention. See *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (“The enablement requirement is met if the description enables any mode of making and using the invention.” (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991))) (emphasis added).

Moreover, Applicant submits that whether Figure 4 and the description thereof (i.e., paragraphs 43 and 44 of the disclosure) *also* enable the invention is beside the point. Indeed, so long as the specification discloses *at least* one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. See *Fisher*, 427 F.2d at 839, 166 USPQ at 24 (CCPA 1970). And, as previously pointed out, *any part of the specification* can support an enabling disclosure, even a background section that discussed, or even disparages, the subject matter disclosed therein. See *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361 1374 , 77 U.S.P.Q.2d 1041, 1051(Fed. Cir. 2005).

Additionally, Applicant submits that the Examiner has mischaracterized what is shown in Figure 4 of Applicant’s disclosure. Figure 4 shows a “*cross-sectional view*” of a luer inserted into the mixture injection port. [See Applicant’s Specification, ¶ 27, page 9, lines 6-7]. Thus, while the septum might “*appear*” to be bent or folded such that only its slit surface might be exposed to circulated fluid – as the Examiner contends – this figure is not a complete view of the deformed septum 130 nor is this what the disclosure describes. In fact, Applicant discloses that the septum 130 is deformed *only in the vicinity of the elongated slit 131* when the luer 190 is inserted therein. [See Applicant’s Specification, ¶ 34, page 12, lines 1-4 (“[W]hen the luer 190 is inserted, the septum 130 in the vicinity of the slit 131 is bended in the insertion direction so that the slit is opened while keeping a substantially airtight state.”), emphasis added]. The septum 130 therefore is not deformed the same about its circumference, such that at least a portion of the back face of the septum exposed, *e.g.*, in region 1142. [See, *e.g.*, Applicant’s

Specification, ¶ 42, page 14, lines 14-17 (“[I]n the region 1141, stagnation of a medical fluid is problematic especially in a region 1142 (FIG. 4), which is a very small gap surrounded by the back face of the septum 130 that has been deformed by insertion of the luer 190 and the wall face of the inner cavity 114.”), emphasis added].<sup>2</sup>

However, solely in an effort to expedite prosecution and in no way acquiescing to the propriety of the rejection, Applicant has amended claim 1 to recite that “a surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate portion to substantially flush away any stagnant matter present on said surface of the septum.” Claims 15 and 21 have been similarly amended. As such, Applicant submits that this limitation of amended claims 1, 15 and 21 is generic to the species illustrated in both Figures 4 and 14, and thus the Examiner’s purported rationale for maintaining this rejection based solely on an elected species is moot.

For at least the foregoing reasons, Applicant submits that the rejection of claims 1, 15 and 21 under 35 U.S.C. § 112, first paragraph, is improper and must be withdrawn.

#### **REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 1, 15 and 21 were rejected under 35 U.S.C. §112, second paragraph as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicant regards as their invention. Applicant traverses this rejection for at least the following reasons.

The Examiner first asserts that in claims 1, 15 and 21 “the limitation that ‘at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate’ is indefinite as it is unclear what element the back surface is exposed to (i.e., to the outside environment, to the interior of the port etc.).” [Office Action, page 4]. Applicant disagrees with this assertion for at least the

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<sup>2</sup> Applicant further notes that paragraphs [0043] and [0044] make no mention that circulating fluid merely contacts the slit surface of the septum, as the Examiner argues, either. Yet, paragraphs [0008]- [0011] specifically mention problems in the art with stagnation and the growth of microorganisms in area 932 on the back surface of the septum 920 illustrated in Figure 1, which the claimed invention seeks to address.

reasons presented in the Reply and Amendment accompanying the Request for Continued Examination ("RCE") filed October 29, 2010, and herein incorporated by reference. However, solely in an effort to expedite prosecution and in no way acquiescing to the propriety of the rejection, Applicant has amended claims 1, 15 and 21, to remove the allegedly indefinite term "*exposed*." Thus, Applicant submits that the Examiner's purported rationale for maintaining this rejection is moot.

In addition, the Examiner asserts that in claims 15 and 21 the limitation "the annular protrusion," allegedly lacks an antecedent basis in the claims. [See Office Action, page 5]. Solely in an effort to expedite prosecution and in no way acquiescing to the propriety of the rejection, Applicant has amended claims 15 and 21, to remove this limitation and to further clarify claimed subject matter. Accordingly, Applicant submits that the basis for this rejection is also moot.

For at least the foregoing reasons, Applicant submits that the rejection of claims 1, 15 and 21 under 35 U.S.C. § 112, second paragraph, is improper and must be withdrawn.

#### **REJECTIONS UNDER 35 U.S.C. § 103**

I. Claims 1, 2, 4, 7, 15, 21, 22 and 25-27 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over U.S. Patent No. 6,193,697 to Jepson, *et al.* (hereinafter "Jepson") in view of U.S. Patent No. 5,441,487 to Vedder (hereinafter "Vedder"). Applicant traverses this rejection for at least the following reasons.

Independent claim 1 recites, *inter alia*, the feature of:

the circulating member is configured to: circulate the first fluid injected from the inserted tube member to a gap region between the inner wall of the channel tube unit and the septum deformed by the insertion of the tube member *such that at least a portion of a surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate portion.*

Independent claim 15 recites the features of:

the edge portion is arranged to further change the direction of flow of the first fluid or the second fluid towards the septum side *such that at least a portion of a surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate portion.*

And, independent claim 21 recites:

the circulating member is separate from the channel tube unit and comprises a plate portion arranged to change direction of flow of the first fluid or the second fluid, and an edge portion that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit *such that at least a portion of a surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate portion.*

[emphasis added].

The rejection is improper for *at least* the reason that the Examiner fails to address the above-emphasized claim features. Indeed. "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) (emphasis added). And this consideration must also include claims limitations which might be indefinite and/or lack support in the original specification (which Applicant does not concede for the reasons discussed above). See MPEP § 2143.03.

To be sure, (i) the Examiner *acknowledges* that Jepson does not teach a circulating plate, and (ii) to the extent that the Examiner relies upon the disk valve (14) of Vedder to allegedly teaches a circulating plate, no mention is made by the Examiner that fluid is redirected by the disk valve 14 to contact a surface of a septum. [Office Action, page 6]. At most, the Examiner merely alleges that asserted combination of Jepson and Vedder would suggest to a skilled artisan:

to modify the port, of Jepson et al., with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a

fluid connection through the port in both first and second fluid flow direction and by closing to prevent fluid flow.<sup>3</sup>

Yet, even assuming *arguendo* that this combination suggests what the Examiner's contends (which Applicant does not concede), the Examiner clearly fails to set forth a *prima facie* case of obviousness of the all the claimed subject matter, including the above-emphasized claim features. See *In re Fitch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992) ("[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.")

Moreover, Applicant submits that the asserted combination of Jepson and Vedder makes no mention or suggestion of using redirected circulating fluid "to substantially flush away any stagnant matter present on said surface of the septum," as amended claims 1, 15 and 21 further recite. For instance, Vedder merely mentions that disk valve 14 opens when the actuator 26 is pushed against it to permit the flow of fluid around disk member 28 and through a lower outlet of the housing 18. [See Vedder, col. 3, lines 43-53].

Thus, for *at least* the foregoing reasons, Applicant submits that Jepson and Vedder, whether taken alone or combination, fail to disclose, teach or otherwise render obvious each and every feature of amended independent claims 1, 15 and 21. As such, claims 1, 15 and 21 are patentable over Jepson and Vedder. Claims 2, 4, 7, 22 and 25-27 ultimately depend from claims 1, 15 and 21, and are patentable for the same reasons as claims 1, 15 and 21 as well as for their additional recitations. Accordingly, the rejection of claims 1, 2, 4, 7, 15, 21, 22 and 25-27 under 35 U.S.C. § 103(a) over Jepson in view of Vedder should be withdrawn and the claims be allowed.

II. Claims 3 and 16 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jepson and Vedder, as applied to claims 2 and 15 above, and further in view of U.S. Patent No. 5,775,671 to Cote (hereinafter "Cote"). Applicant traverses this rejection for at least the following reasons.

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<sup>3</sup> *Id.*

As discussed above, the asserted combination of Jepson and Vedder does not teach or otherwise render obvious each and every feature of independent claims 1 and 15. Moreover, the Examiner merely relies upon Cote to allegedly teach features of the dependent claims.

Thus, for *at least* the foregoing reasons, Applicant submits that Jepson, Vedder, and Cote whether taken alone or combination, fail to disclose, teach or otherwise render obvious each and every feature of amended independent claims 1 and 15. Claims 3 and 16 ultimately depend from claims 1 and 15, and are patentable for the same reasons as claims 1 and 15 as well as for their additional recitations. Accordingly, the rejection of claims 3 and 16 under 35 U.S.C. § 103(a) over Jepson in view of Vedder and further in view of Cote should be withdrawn and the claims be allowed.

III. Claim 5 was rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jepson and Vedder, as applied to claim 4 above, and further in view of U.S. Patent No. 5,817,069 to Arnett (hereinafter "Arnett").

As discussed above, the asserted combination of Jepson and Vedder does not teach or otherwise render obvious each and every feature of independent claims 1 and 15. Moreover, the Examiner merely relies upon Arnett to allegedly teach features of a dependent claim.

Thus, for *at least* the foregoing reasons, Applicant submits that Jepson, Vedder and Arnett, whether taken alone or combination, fail to disclose, teach or otherwise render obvious each and every feature of amended independent claim 1. Claim 5 ultimately depends from claim 1, and is patentable for the same reasons as claim 1 as well as for its additional recitations. Accordingly, the rejection of claim 5 under 35 U.S.C. § 103(a) over Jepson in view of Vedder and further in view of Arnett should be withdrawn and the claim be allowed.



**CONCLUSION**

Having addressed each of the foregoing objections and rejections, it is respectfully submitted that a full and complete response has been made to the outstanding Office Action and, as such, the application is in condition for allowance. Notice to that effect is respectfully requested.


If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

If an extension of time is necessary to prevent abandonment of this application, then such an extension of time is hereby petitioned for under 37 C.F.R. §1.136(a). Any fees required (including fees for net addition of claims) are hereby authorized to be charged to **Deposit Account No. 033975** (Ref. No. **061639-0318680**).

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Respectfully submitted,

By:



E. Rico Hernandez  
Registration No. 47,641

**Customer No.: 00909**

Pillsbury Winthrop Shaw Pittman LLP  
P.O. Box 10500  
McLean, Virginia 22102

Direct: (703) 770-7788  
Main: (703) 770-7900  
Fax: (703) 770-7901